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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON
PORTLAND DIVISION

Melanie Crites-Bachert, Plaintiff, v. **Providence Health & Services - Oregon** Defendant.	Case No.: 3:23-cv-1510-YY **AMENDED COMPLAINT** **Demand for Jury Trial**

INTRODUCTION

1. This case is about blatant violation of constitutional, statutory, contractual, and tort rights perpetrated by Providence Health & Services – Oregon ("Providence") against Dr. Melanie Crites-Bachert ("Crites-Bachert"). As a hospital system, expert in human health and pharmaceuticals, Providence knew very well that the COVID-19 vaccines were ineffective and extraordinarily dangerous. Providence knew very well that

experimental medications may not be mandated. Providence knew very well that it could not discriminate against Crites-Bachert on the basis of religion. Yet, Providence violated all these principles thereby overturning Crites-Bachert's life, sense of wellbeing, and plans for the future. Crites-Bachert has suffered significant damages due to Providence's wrongdoing.

PARTIES

2. Among other things, Dr. Melanie Crites-Bachert ("Crites-Bachert") is a Doctor of Osteopathic Medicine, a surgeon, and an inventor, who maintained privileges at Providence as a Professional Staff Member since 2011 at Providence Milwaukie Hospital, Providence Portland Medical Center, and Providence St. Vincent Medical Center.

3. Providence is a domestic non-profit corporation operating a group of hospitals registered to do business in Oregon with its principal place of business in Renton, Washington.

JURISDICTION

4. This action arises under federal law 42 U.S.C. § 1983, the United States Constitution, and 21 U.S.C. § 360bbb-3, which protect the rights, privileges, and immunities secured to Plaintiff.

5. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1343. This Court has personal jurisdiction over Providence because it has

committed acts in this district that violate the rights of Crites-Bachert protected by the Constitution and the laws of the United States and Oregon.

6. This Court has pendent jurisdiction over the state law claims arising from the same facts and circumstances giving rise to the federal claims.

BASIS FOR COMPLAINT

A. The Harm to Crites-Bachert.

7. Crites-Bachert is a Doctor of Osteopathic Medicine and a surgeon with operating privileges at Providence as a Professional Staff Member until her suspension in 2021 for refusing to take a COVID-19 vaccine.

8. Providence mandated that all Professional Staff Members receive a COVID-19 experimental vaccine to continue their association with Providence.

9. Crites-Bachert has a bona fide religious conviction that prevents her from taking one of the COVID-19 vaccines due the use of fetal cell lines and the moral duty in her faith to follow her conscience. Crites-Bachert sought a religious exemption which included a letter from her Pastor, Reverend David Burton Kimbal. Providence approved Crites-Bachert's religious exemption.

10. Then, without cause, Providence changed their position and denied Crites-Bachert's religious exemption. Providence refused to give any explanation for why they rejected Crites-Bachert's religious exemption after first approving it. Crites-Bachert immediately appealed the decision. Her appeal was denied on October 15, 2021. Providence wrongfully denied a religious exemption to Crites-Bachert.

11. Crites-Bachert had a thriving urology practice with hundreds of surgeries performed and with many hundreds more prospective surgeries to be performed in future years through her career. Crites-Bachert was the most sought-after and prolific surgeon in Oregon in her specialty. Due to Providence's violation of Crites-Bachert's rights, she has had to quit her business in Oregon and leave the State of Oregon to practice medicine. She now practices in Ohio and Arizona traveling across the country every week in order to make a living.

12. Crites-Bachert was a partner in the Plaza Ambulatory Surgery Center, LLC. Providence was well-aware of Crites-Bachert's partnership because it was also a partner of the Surgery Center. When Providence denied Crites-Bachert's exemption, the Surgery Center would no longer allow her to do surgeries. Crites-Bachert has to resign her partnership due to Providence's wrongful denial of her religious exemption.

13. The illegal actions by Providence turned Crites-Bachert's life upside down, destroying her peace of mind, and causing severe emotional distress.

14. Providence had an obligation not to violate Crites-Bachert's civil rights and discriminate against her. Providence's adverse actions against Crites-Bachert were not to protect against an unacceptable health and safety risk. Providence knew at the time that it damaged Crites-Bachert that the COVID-19 vaccines were completely ineffective and were unacceptably dangerous. Providence sought to receive monetary incentives if all employees and Medical Staff were vaccinated. Given the choice of violating Crites-Bachert's rights and money, Providence chose money.

15. In addition to choosing money over the health and welfare of Crites-Bachert and other Medical Staff and employees, Providence's hypocrisy was without bounds. At the very same time that Providence terminated Crites-Bachert's privileges for refusing to take an experimental COVID-19 vaccine it was hiring new employees without requiring them to have taken the experimental COVID-19 vaccine.

16. Because of Providence's unlawful adverse employment actions against Crites-Bachert, Crites-Bachert has suffered economic loss, loss of reputation, and severe emotional distress. Standing by her religious convictions cost Crites-Bachert dearly.

B. Background.

17. The laws regulating the investigational new drug (IND) industry were largely created after Senator Edward Kennedy held live hearings in 1973 detailing the industry's abuses against the American people. In 1974, Congress enacted the National Research Act[1] in response to those hearings, establishing laws, regulations, and mandatory guidelines to protect Americans from future abuses. However, the industry has been internally regulated and enforced via various federal and state agencies since 1974. This internal enforcement has denied the judiciary from acquiring knowledge of the laws discussed herein.

[1] Public Law 93-348 - July 12, 1974 National Research Act

18. The 1974 National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research[2] (hereinafter referred to as the "Commission").

19. Congress required the Commission to:

A. "conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects,"

B. "develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles," and

C. "make recommendations to the [HHS] Secretary" for "such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary."

20. Congress further required the Commission to consider "the nature and definition of informed consent in various research settings."[3]

21. On April 18, 1979, the Commission published its findings in the Federal Register in a report titled, "The Belmont Report."[4]

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[2] Title II of the National Research Act, Public Law 93 - 348-July 12, 1974 - https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf

[3] National Research Act Title II - PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVORIAL RESEARCH Part A Section 202. (a)(1)(B)(iv)

[4] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. - Belmont Report. Colorado, DC: U.S. Department of Health and Human Services,1979

[5] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. - Belmont Report. Colorado, DC: U.S. Department of Health and Human Services,1979

23. The Belmont Report outlined what the Commission considered "the nature and definition of informed consent" as follows:

A. "An autonomous person is an individual capable of deliberation about personal goals and acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons 'considered opinions and choices while refraining from obstructing their actions…" (Emphasis added);

B. "To show lack of Respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments…"(Emphasis added);

C. "Respect for persons requires subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied" (Emphasis added).

24. The Belmont Report defined those adequate standards of informed consent as follows:

A. An agreement to participate in research constitutes valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence; (Emphasis added)

B. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance;

C. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable;

D. Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject," (emphasis added), and;

E. …undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and

> threatening to withdraw health services to which an individual would otherwise be entitled.

25. The Commission determined that if an individual is under outside pressure to participate in an investigational medical activity, then obtaining that individual's informed consent was legally impossible.

26. Congress mandated in the National Research Act that "[i]f the Secretary determines that administrative action recommended by the Commission should be undertaken by him, he shall undertake such action as expeditiously as is feasible."

27. Congress required the HHS Secretary to act upon the Commission's recommendations as outlined in the Belmont Report by establishing regulations to protect humans involved in biomedical research activities. **Therefore, given the complexity, the intent of Congress was not to draft those laws but to allow the HHS Secretary to promulgate regulations on its behalf** to protect humans involved with investigational drugs. Therefore, these regulations are unique in that they were expressly requested by Congress to fulfill the intent of Congress via the National Research Act.

28. In the early 1980s, HHS acted upon the Commission's recommendations, stating, "Based on the Belmont Report and other work of the National Commission, HHS revised and expanded its regulations for protecting human subjects…The HHS regulations are codified at 45 Code of Federal Regulations (CFR) 46, subparts A through D."[6]

[6] 45 CFR 46 FAQs. HHS.gov. Published 2018. Accessed May 18, 2023. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html

2. 45 CFR Part 46

29. 45 CFR Part 46 is entitled, "Protection of Human Subjects." Subpart A is entitled, "Basic HHS Policy for Protection of Human Research Subjects" and establishes that (a) the policy (for protection of human research subjects) "applies to **all research**[7] involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency..." (Emphasis added).[8]

30. HHS designed a very broad definition of research when, at 45 CFR § 46.102 (Definitions): "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes"[9] (emphasis added). Research under this policy includes medical chart reviews by students or periodic studies of medical products under 21 U.S.C. §360bb-3 authorization.[10]

31. A "human subject" is broadly defined as (1) a living individual, (2) from whom data is obtained and used,[11] and (3) from whom identifiable private information is known.[12]

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[7] Research under 45 CFR Part 46 includes clinical trials but is not limited in scope to only clinical trials. College students studying medical charts of patients constitutes "research" requiring 45 CFR Part 46 adherence.
[8] 45 CFR 46.101(a)
[9] 45 CFR 46.102(l)
[10] https://www.hhs.gov/ohrp/sites/default/files/human-subject-regulations-decision-charts-2018-requirements.pdf
[11] 45 CFR 46.102(e)(1)(i)
[12] 45 CFR 46.102(e)(1)(ii)

32. HHS regulations define[13] the term "human subject" at 45 CFR 46.102(e) as follows:

> (1) ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research:
>
> > (i) Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or
> >
> > (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
>
> (2) ***Intervention*** includes physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
>
> (3) ***Interaction*** includes communication or interpersonal contact between investigator and subject.
>
> (4) ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
>
> (5) ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the information.

[13] "Coded Private Information or Biospecimens Used in Research (2018)." HHS.gov. Published January 19, 2018. https://www.hhs.gov/ohrp/coded-private-information-or-biospecimens-used-research.html#:~:text=Identifiable%20private%20information%20is%20private,is%20associated%20with%20the%20information (Last accessed June 5, 2023)

> (6) ***An identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the biospecimen. (Emphasis in original.)

33. Congress drafted broad definitions for "research and "subjects" to comply with the recommendations of the Belmont Report, which declared that "the general rule is that if there is any element of research in an activity, that activity should undergo review (third-party review to ensure the health and rights of involved individuals are protected) for the protection of human subjects"[14]

34. Accordingly, if individuals are administered an investigational medical product and their private identifiable information is collected along with the details about their interaction with the product, and that information is monitored, studied, or analyzed for purposes of adding to the generalizable knowledge of the product, then the activity meets the definition of "research," requiring 45 CFR Part 46 compliance.

35. HHS ensured that all research activities involving the federal government must comply with Belmont Report's ethical requirements: (1) "Department or agency heads retain final judgment as to whether a particular activity is covered by this policy, and this judgment shall be exercised consistent with the ethical principles of the Belmont Report"[15] (emphasis added), (2) if the activity is considered exempt from the policy, then

[14] The Belmont Report Part A: Boundaries Between Practice & Research. "Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects." (emphasis added).

[15] 45 CFR § 46.101(c)

"the alternative procedures to be followed are consistent with the principles of the Belmont Report."[16]

36. Congress expressly prohibits the federal government from administering an investigational product to an individual without complying with the Belmont Report's ethical principles and 45 CFR § 46.101, *et seq*.

37. Placing an individual under a "sanction" for refusing an EUA drug, biologic, or device patently violates the ethical principles of the Belmont Report.

38. The intent of Congress was to give the Belmont Report the force of law through 45 CFR § 46.101, *et seq*. and the Federal Wide Assurance agreement (see discussion, *infra*) for the explicit purpose of protecting humans when they are offered a federally funded EUA investigational product.

39. To further protect Americans from medical research abuses in the future, Congress declared that "Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied."[17]

40. Moreover, Congress also prohibited the United States Military from abusing individuals again by enacting 10 U.S.C. § 980(a), which provides in pertinent part, "Funds appropriated to the Department of Defense may not be used for research

[16] 45 CFR § 46.101(i)
[17] 45 CFR § 46.122. All COVID-19 EUA drugs and their administration have been fully funded by the federal government, requiring adherence to 45 CFR Part 46.

involving a human being as an experimental subject unless — (1) the informed consent of the subject is obtained in advance."

41. Therefore, pursuant to 45 CFR § 46.101, *et seq*., "research" occurs when an individual is administered an investigational drug, the individual's private identifiable information is known, and data collected regarding their interaction with the drug is added to the generalizable knowledge about the drug.

42. The COVID-19 CDC Vaccination Program is a research activity requiring 45 CFR § 46.101, *et seq*. compliance as well as each COVID-19 EUA's Scope of Authorization.

43. At no time may the federal government offer or administer an investigational medical product to an individual if their "legally effective informed consent" is not obtained in advance.

3. Legally Effective Informed Consent

44. 45 CFR § 46.116 sets forth the Belmont Report's "adequate standards" of informed consent[18], and they include, but are not limited to:

> (a)(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative; (Emphasis added)
>
> (a)(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and

[18] The Belmont Report and 45 CFR §46.116 contain the only definition for what Congress deems legally effective informed consent. Therefore, when statutes explicitly or implicitly mandate a person to give their legally effective informed consent, these definitions must be understood as the intent of Congress for compliance purposes.

consider whether or not to participate and that minimize the possibility of coercion or undue influence; (Emphasis added)

(a)(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject;

(a)(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information;

(a)(5) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research;

(a)(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights;

(a)(7) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs…;

(a)(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. (Emphasis added)

45. Legally Effective Informed Consent, according to the Belmont Report, can be broken down into its basic formula as:

A. the individual must not be under outside pressure to participate,

B. the only reason an individual participates is that he or she believes the product may benefit their personal health goals, and

C. the conditions of 1 and 2 are established before the individual participates in the investigational product.

46. Only when authorities comply with 45 CFR § 46.101, *et seq*. and the ethical principles of the Belmont Report can an opportunity exist for an individual to give their legally effective informed consent according to 45 CFR § 46.116(a)(1).

47. Informed Consent must be legally effective and prospective, according to HHS.

48. 45 CFR Part 46 applies to all federal agencies, departments, and the military (45 CFR § 46.101(a)). Additionally, twenty federal agencies incorporated 45 CFR Part 46 specifically into their regulatory framework.[19]

49. Through the Federal Wide Assurance (FWA) agreement (see *infra*), all U.S. States and Territories (i.e., state health agencies have FWA agreements) have agreed to obtain the legally effective informed consent of individuals when involving them in investigational medical products.

50. Consensual medical experimentation involving investigational medical products can only exist under conditions that ensure individuals are free from outside pressures to participate.

51. Therefore, individuals have the explicit right to refuse an investigational drug, biologic, or device without incurring a penalty or loss of benefits to which they are otherwise entitled.

[19] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

52. When Providence penalized Crites-Bachert for refusing to inject a 21 U.S.C. §360bbb-3 investigational drug into their bodies, Providence violated its obligation to obtain Crites-Bachert's legally effective informed consent.

4. ICCPR Treaty

53. In 1992, the United States Senate ratified the International Covenant on Civil and Political Rights Treaty (ICCPR).[20] Article 7 states, "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, ***no one shall be subjected without his free consent to medical or scientific experimentation***."

54. Subjected means to be under the rule of law by one's authority.

55. Free consent means to be free from outside pressures to participate.

56. The U.S. Senate issued a resolution stating, "That the United States considers itself bound by Article 7 to the extent that 'cruel, inhuman or degrading treatment or punishment' means the cruel and unusual treatment or punishment prohibited by the Fifth, Eighth and/or Fourteenth Amendments to the Constitution of the United States."[21]

57. The U.S. Senate considered it to be a violation of Article 7 of the ICCPR Treaty and the 5th Amendment's Due Process Clause if individuals were forced to forfeit liberty and property without due process for refusing medical experimentation. The

[20] Treaty Document 95-20 - *International Covenant On Civil and Political Rights*, https://www.congress.gov/treaty-document/95th-congress/20/all-info.
[21] See "Resolution" – Treaty Document 95-20 - *International Covenant On Civil and Political Rights*. https://www.congress.gov/treaty-document/95th-congress/20/all-info.

Senate also considered it to be a violation of Article 7 of the ICCPR Treaty and the 14th Amendment's Equal Protection Clause when individuals who refused medical experimentation were treated differently than those who accepted medical experimentation.

58. The United States Senate stated that Articles One through Twenty-Seven of the ICCPR Treaty are not "self-executing" but "that it is the view of the United States that States Party to the Covenant should, wherever possible, refrain from imposing any restrictions or limitations on the exercise of the rights recognized and protected by the Covenant, even when such restrictions and limitations are permissible under the terms of the Covenant."

59. No justification or extenuating circumstances may be invoked to excuse a violation of Article 7 for any reasons, including those based on an order from a superior officer or public authority. Under Article 4, there may be no derogation of the Article 7 right to informed consent without duress or coercion.

5. Emergency Use Authorization

60. Congress prohibits persons from introducing drugs and biologics into commerce before receiving an FDA marketing license.[22]

61. However, for limited reasons of compassion, education, and emergency use, Congress provides a legal mechanism to allow persons to participate in the

[22] 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.").

investigational and unlicensed use of drugs, biologics, and devices according to the product's labeling, known as "expanded access protocols."[23]

62. "Unlicensed use" means the use of a medical product for a purpose not licensed by the FDA (legal indication, usage, and contraindications) according to the product's labeling.

63. Investigational "means a new drug or biological drug that is used in a clinical investigation."[24]

64. Clinical investigation "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice."[25]

65. Only the FDA can assign a drug, biologic, or device its legal indication and classification. A drug, biologic, or device is legally governed by its classification and FDA-licensed indication, usage, and contraindication.

66. Congress expressly authorized only the HHS Secretary to authorize expanded access protocols for the investigational and unlicensed use of drugs, biologics, and devices.[26]

[23] 21 U.S.C. § 360bbb *et. seq.* Short Title: "Expanded Access to Unapproved Therapies and Diagnostics"
[24] 21 CFR 312.3 ("Investigational new drug").
[25] 21 CFR 312.3 ("Clinical investigation").
[26] 21 U.S.C. §360bbb(a)

67. Congress enacted Project Bioshield[27] in 2004, establishing emergency expanded access protocols[28] for the investigational and unlicensed emergency use of drugs, biologics, and devices for large populations.

68. Medical products authorized under 21 U.S.C. §360bbb-3 are known as medical countermeasures (MCMs)[29] and are exempt from 21 U.S.C. § 355(a) during the declared emergency.

69. A drug or biologic under EUA/EUI is considered investigational, and, as a matter of law, it cannot have a licensed indication for its emergency use.[30]

70. Providence concealed Crites-Bachert's rights to refuse administration of an EUA, EUI, or PREP Act product.

71. Individuals who consent to participate in the administration of a 21 U.S.C. §360bbb-3 product or PREP Act countermeasure must agree to the following terms and conditions, including but not limited to: (1) forfeiture of civil litigation rights resulting from injuries;[31] (2) allowing their private identifiable information to be collected and used for a variety of purposes by unknown persons;[32] (3) allow their involvement with the EUA product to be cataloged by various persons for unknown purposes, (4) allow the data collected about their adverse events to be utilized by researchers for unknown

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[27] https://www.govinfo.gov/content/pkg/PLAW-108publ276/pdf/PLAW-108publ276.pdf
[28] 21 U.S.C. § 360bbb-3
[29] National Defense Authorization Act 2004 TITLE XVI—DEFENSE BIOMEDICAL COUNTERMEASURES https://www.govinfo.gov/content/pkg/PLAW-108publ136/pdf/PLAW-108publ136.pdf
[30] 21 U.S.C. §360bbb-3(a)(2)(A,B)
[31] PREP Act forfeits all civil actions for damages in most situations.
[32] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to obtain private identifiable information.

purposes and for eternity,[33] (5) assume greater risks to their safety, health, and legal rights.[34]

72. Providence enacted a vaccination polity but exclusively relied on non-vaccines for compliance.

73. Providence did not inform Crites-Bachert that the federally owned EUA drugs they relied upon were not licensed by the FDA nor classified as a "vaccine."

6. The PREP Act

74. In 2005, Congress passed the Public Readiness and Emergency Preparedness Act, hereafter referred to as the PREP Act,[35] to provide immunities for persons volunteering for "covered" activities.

75. In accordance therewith, the HHS Secretary issued a PREP Act declaration for Medical Countermeasures against COVID-19 in February 2020.[36]

76. All COVID-19 drugs, influenza vaccines, masks, and diagnostic testing articles under Providence's Policy's requirements were declared a countermeasure under the PREP Act.[37]

77. The PREP Act, fundamentally, is an immunity statute.

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[33] Each EUA and/or the CDC COVID-19 Vaccination Program Provider Program requires manufacturers and/or emergency stakeholders to monitor, report and study a variety of adverse reactions to EUA products.

[34] 21 U.S.C. §360bbb-3 requires potential recipients to be made aware of the risks, alternatives, and the fact that the product is only authorized by the Secretary under emergency conditions. These elements provide potential recipients with the required information to make a quality and legally effective decision to consent. Therefore, consent means the individual agrees to assume more than minimal risk as defined in 21 CFR 50.3(k).

[35] 42 U.S.C. 247d-6d & 42 U.S.C. 247d-6e

[36] 85 FR 15198

[37] See Amendments I-XI of 85 FR 15198

78. Due to the near absolute immunities provided by the U.S. Congress for persons involved in the various activities of "covered countermeasures," the statute establishes restrictions, obligations, and duties for persons and governments involved in those activities.

79. Congress expressly crafted language preempting state and local law conflicting with the PREP Act,[38] which provides, in pertinent part:

(8) Preemption of State law

> During the effective period of a declaration under subsection (b)…no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> (A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (B) relates to the…administration…of the covered countermeasure, ***or to any matter included in a requirement applicable to the covered countermeasure*** under this section or any other provision of this chapter, ***or under the Federal Food, Drug, and Cosmetic Act***.[39]

80. The "voluntary nature" of the "program" consists of "covered countermeasures,"[40] "covered persons,"[41] "covered individuals,"[42] and "qualified persons."[43]

81. No person may utilize any lawful authority to "establish," "enforce," or "continue in effect with" "any provision of law or legal requirement" that otherwise

[38] 42 U.S.C. § 247d-6d(b)(8)
[39] 42 U.S.C § 247d-6d (emphasis added).
[40] 42 USC § 247d-6d(i)(1)
[41] 42 USC § 247d-6d(i)(2)
[42] 42 USC 247d-6d(a)(3)(C)(i,ii)
[43] 42 USC § 247d-6d(i)(8)

conflicts or interferes with the "voluntary nature" of the program by establishing involuntary conditions such as Providence's Policy.

82. No person may utilize any lawful authority to "establish," "enforce," or "continue in effect with" "any provision of law or legal requirement" that interferes with "any matter" relating to any "requirement applicable to the covered countermeasure" under 21 U.S.C. §360bbb-3 which includes a person's authority to accept or refuse the MCM without consequence.[44]

83. Congress completely preempts a state, or political subdivision of a state, or any other legal authority from establishing, enforcing, or continuing in effect with respect to a countermeasure under the PREP Act, any provision of law that is different from or is in conflict with, any requirement applicable under the statute or the declared emergency and its amendments as published in the Federal Register.

84. Providence was expressly preempted from using its position of influence and authority for the sole purpose of interfering with Crites-Bachert's authority to determine participation in a PREP Act "covered countermeasure."

85. Providence's Policy, as applied, required Crites-Bachert to inject or otherwise use a PREP Act countermeasure as a condition to enjoy a benefit to which they were otherwise entitled.

[44] 42 U.S.C. § 247d-6d(b)(8)(b) states to any matter or requirement applicable to a countermeasure under the FDCA. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) is under the FDCA.

86. When Crites-Bachert refused to surrender her statutory authority to refuse the countermeasure's administration, Providence, acting with moral turpitude, informed her that she would lose her privileges and liberties.

7. EUA Precedent

87. On January 28, 2005, HHS issued the first EUA[45] under its new Section 564 authority (21 U.S.C. 360bbb-3) for an experimental anthrax vaccine. HHS stated, "***The issuance of this Authorization for the emergency use of [Anthrax Vaccine] is the first time that the EUA authority is being used***. FDA intends to explain clearly the reasons for each issuance, termination, or revocation of an EUA. The agency wishes to make its decision-making understandable to help ensure that members of the public, and particularly those individuals who may be eligible to receive a medical product authorized for emergency use, are informed about the basis of an EUA determination."[46]

88. The Notice explicitly cited the Section 564 informed requirement in Section 564 of "the option to accept or refuse administration of AVA; of the consequences, if any, of refusing administration of the product; and of the alternatives to AVA that are available, and of their benefits and risks."

89. The Notice further provided: "Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel

[45] https://www.govinfo.gov/content/pkg/FR-2005-02-02/pdf/05-2028.pdf
[46] 70 Fed. Reg. 5452, HHS Notice, *Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability* (Feb. 2, 2005) (emphasis added).

action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination."[47]

90. The human right explained in the 2005 experimental anthrax vaccine Notice[48] is exactly the right that Crites-Bachert was entitled to with respect to the COVID-19 vaccines.

8. Federal Wide Assurance (FWA)

91. In 2001, HHS created the Office of Human Rights Protection (OHRP), which established the Federal Wide Assurance (FWA) agreement. The FWA is an agreement by entities conducting business with HHS to comply with 45 CFR 46 and the Belmont Report's ethical guidelines.

92. HHS states,

> The Federal Wide Assurance (FWA) is an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS). The FWA is also approved by OHRP for federal wide use, which means that other U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research they conduct or support.
>
> An FWA is the only type of assurance currently accepted and approved by OHRP. It is required whenever an Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule…"[49]

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[47] 70 Fed. Reg. 5452, 5455.
[48] 70 Fed. Reg. 5452.
[49] HHS, Office for Human Research Protections, *Federal Wide Assurance Instructions*, https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/fwa-instructions/index.html (viewed Jan. 9, 2023).

93. The OHRP assigns an FWA identification number to entities (hereinafter referred to as "Contracting Provider") that fulfill application requirements.

94. An FWA identification number is issued only after the legally binding agreement between the Contracting Provider and the United States government has been signed.

95. Providence has signed at least one FWA, FWA00001033.

96. The FWA's main purpose is to benefit a third-party beneficiary because the FWA agreement authorizes the Contracting Provider to participate in federally funded programs involving humans with investigational drugs if, and only if, the Contracting Provider agrees to protect the health and legal rights of the third-party beneficiaries (i.e., humans who are administered investigational drugs, biologics, or devices under the research conditions described above.

97. Each FWA agreement hinges upon protecting the rights of third-party beneficiaries. Providence has a fiduciary duty to the third-party beneficiaries under the terms of its FWA agreements.

98. The intended benefit to the third-party beneficiary is the right to accept or refuse participation in investigational products, clinical trials, and other research activities without fearing consequences for refusal and to know that independent Institutional Review Boards will provide oversight, ensuring their health, safety, and rights are protected.

99. The FWA agreement requires the Contracting Provider to ensure that no third-party beneficiary is under outside pressure to participate in an investigational drug, biologic, or medical device.

100. The FWA agreement requires Providence to assure potential participants that they will not incur a penalty or lose a benefit to which they are otherwise entitled when refusing participation.[50]

101. Crites-Bachert is an intended third-party beneficiary of Providence's FWA agreement, and her rights were violated the moment Providence penalized Crites-Bachert for refusing to take a COVID-19 vaccine.

102. The FWA holds third-party benefits for Crites-Bachert.[51] For each duty placed upon Providence, a corresponding right exists for Crites-Bachert. Providence is required to obtain informed consent: "Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative."[52] The duty upon Providence to obtain legal consent establishing the right of Crites-Bachert to give it.

103. Providence is well aware, or should be aware, through its existing Institutional Review Boards, decades-long use of protocols under 21 U.S.C. §360bbb *et.*

[50] "The Federal Wide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46." - HHS. 45 CFR 46.116(b)(8) requires the individual to be informed they will not be penalized for refusing participation in a research activity.
[51] 45 CFR § 46.116.
[52] 45 CFR 46.116(a)(1).

seq., FWA, and signed CDC COVID-19 Vaccination Program Provider Agreement, they must obtain Crites-Bachert's legally effective informed consent before involving them in a federally funded research activity.

104. The FWA, Belmont Report, and 45 CFR Part 46 exist exclusively to prevent medical research abuses such as Providence's Policy denying Crites-Bachert authority to give her legally effective informed consent.

105. Providence assured the federal government that it would effectively perform the duties owed to Crites-Bachert in a federally funded research program, and Providence violated those duties when requiring involuntary participation in the CDC COVID-19 Vaccination Program.

106. Providence assured HHS that they would comply with the Belmont Report and 45 CFR Part 46 through its FWA anytime it involved a human with a federally funded medical research activity[53] as a condition to access federal funding.

107. Upon information and belief, Providence received federal funding related to the COVID-19 pandemic.

108. Providence was aware of, or should have been aware, that at no time were they allowed to place an individual under a "sanction," "coercion," "undue influence," or

[53] The CDC COVID-19 Vaccination Program requires Oregon and authorized providers to conduct joint research activities involving humans with the federally funded COVID-19 EUA drugs. Monitoring and reporting of adverse events are required under 21 U.S.C. §360bbb-3, the CDC COVID-19 Vaccination Program Provider Agreement, and the Scope of Authorization for each EUA drug. Moreover, it isn't only persons signing the CDC COVID-19 Vaccination Program but persons also acting as "stakeholders" under the Scope of Authorization for each EUA drug.

"unjustifiable pressures" to participate in federally funded research activities such as the CDC COVID-19 Vaccination Program.

109. Although Providence might not have administered COVID-19 vaccines to any of the persons under its Policy, it established conditions requiring Crites-Bachert to participate in a federally funded research activity in violation of its FWA.

9. CDC COVID-19 Vaccination Program Provider Agreement

110. Before the CDC accepts a person or entity as a Provider in the CDC Vaccination Program, that person or entity is required to sign the CDC COVID-19 Vaccination Program Provider Agreement.[54] The agreement provides: "Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement (Section A)."[55]

111. Providence signed at least one of these CDC COVID-19 Vaccination Program Provider Agreements.

112. By signing the agreement, Providence agreed that was working in collaboration with the Oregon and its agreement with the CDC. This requirement of the COVID-19 Vaccination Program Provider Agreement makes Providence a state actor.

113. HHS requires any entity conducting business with its organization to submit and be approved for a Federal Wide Assurance agreement (see discussion, *supra*)

[54] Exhibit 9.
[55] *Id*.

in advance of participating in any program involving humans with investigational drugs under its authority. The purpose of the CDC going through the voluntary participation of States is because each state already had a Federal Wide Assurance agreement in place requiring compliance with the same laws as a condition upon the State to access federal funding.

114. The COVID-19 Vaccination Program is a federally funded program designed to distribute investigational new drugs that were under 21 U.S.C. §360bbb-3 EUA authorization.

115. The Provider Agreement requires that all volunteer participants:

A. must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative,

B. Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS),

C. Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine,

D. Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.

116. The EUA Fact Sheet is required because the Executive Branch of the government is the sole sponsor of EUA products, and federal law requires them to obtain the legally effective informed consent of each individual before the administration of the product.

117. The requirement that the "Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws" is because federal law declares:

A. "This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects" (45 CFR 46.101(f));

B. Additionally, federal law declares, "The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective" (45 CFR 46.116(i));

C. This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research (45 CFR 46.101(g))

118. The Provider Agreement required Providence to acknowledge the law before acceptance, as follows: "By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine ***understand and will comply*** with the agreement requirements listed above…"[56]

119. Providence and Oregon agreed to participate in a joint effort to conduct research activities and obtain the legally effective informed consent of individuals on behalf of the United States Government when signing the CDC COVID-19 Vaccination Program Provider Agreement.

[56] Exhibit 9 (emphasis added).

10. COVID-19 Research Activities

120. The State and public and private parties it authorizes for the CDC Vaccination Program are in a symbiotic relationship to conduct 45 CFR § 46.101, *et seq*. research activities pertaining to COVID-19 EUA drugs, biologics, and devices on behalf of the federal government. Moreover, they are in a symbiotic relationship to obtain legally effective informed consent from individuals offered participation in those experimental medical products.

121. The federal government's Executive Branch purchased all COVID-19 EUA drugs and, in conjunction with the HHS Secretary[57] and the CDC, developed research activities that States and CDC Vaccination Program Providers must conduct on its behalf

122. Drugs, biologics, and devices authorized under 21 U.S.C. §360bbb-3 are classified by the FDA as investigational (experimental),[58] according to their labeling. They have no legal indication to treat, cure, or prevent any disease according to their labeling.

123. At all pertinent times, the only COVID-19 drugs available for compliance with Providence's COVID-19 Vaccine Policy were FDA-classified investigational new

[57] The EUA Scope of Authorization assigns research activities to the person acting on behalf of the manufacturer of the drug (the federal government who purchased all of the inventory), and to "emergency stakeholders," and "health care providers."

[58] Investigational new drug means, "A substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people…Also called experimental drug, IND, investigational agent, and investigational drug." NCI Dictionary of Cancer Terms. National Cancer Institute. Published 2023. Accessed June 25, 2023. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/investigational-new-drug. See "Investigational new drug" and "Clinical investigation" Note that "clinical investigation" is distinct from "clinical trial." While all clinical trials are clinical investigations, not all clinical investigations are clinical trials. 21 CFR 312.3

drugs wholly owned by the federal government and only distributed through a federally funded program.

124. Investigational new drugs are legally regulated entirely differently than licensed drugs. The FDA declared in its August 23, 2021 EUA to Pfizer that "Pfizer-BioNTech COVID-19 Vaccine" drug is legally distinct from its licensed "COMIRNATY" drug.[59]

125. Investigational drug "means a new drug or biological drug that is used in a clinical investigation."[60] Clinical investigation "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, ***an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice***."[61]

126. Drugs are governed by their classification according to their labeling and not by their formulation.

127. Congress explicitly enacted laws governing investigational new drugs to prevent the executive branch from continuing its history of abusing the rights of individuals who participate in federally funded investigational medical products.

128. 21 U.S.C. §360bbb-3 requires the Secretary of HHS to establish "[a]ppropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product."[62]

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[59] *See* Exhibit 8, FDA EUA Letter to Pfizer, August 23, 2021.
[60] 21 CFR 312.3 "Investigational new drug"
[61] 21 CFR 312.3 "Clinical investigation" (emphasis added).
[62] 21 U.S.C. §360bbb-3(e)(1)(A)(iii).

129. The Secretary establishes the conditions under which the research activities will occur in each EUA letter, known as the Scope of Authorization.

130. As an example, on January 19, 2021 the Secretary established mandatory conditions that Pfizer and emergency stakeholders (distributors, manufacturers, etc.) must follow, which involve 45 CFR 46 research activities.[63]

131. Under the EUA's "Conditions of Authorization," the Secretary mandates among other things:

> F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
>
> - Serious adverse events
> - Cases of Multisystem Inflammatory Syndrome in children and adults
> - Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer, Inc.
>
> G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals, within 15 days after the last day of a month…Each periodic safety report is required to contain descriptive information which includes:
>
> - A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest.
> - Newly identified safety concerns in the interval.
>
> N. Pfizer Inc. will conduct post-authorization observational study(ies) to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (16 years of age and older), populations

[63] 86 Fed. Reg. 5200, HHS, *Authorizations of Emergency Use of Two Biological Products During the COVID–19 Pandemic; Availability* (Jan. 19, 2021).

> of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities.
>
> T. Vaccination providers administering Pfizer-BioNTech COVID-19 Vaccine must report the following information…to VAERS…:
>
> - Serious adverse events
> - Cases of Multisystem Inflammatory Syndrome in children and adults
> - Cases of COVID-19 that result in hospitalization or death[64]

132. VAERS reported 1,562,008 entries from December 2020 through May 26, 2023, including 35,272 deaths (1.6 per hour) and 263,462 (12.11 per hour) serious injuries. These numbers demonstrate historical entries for a drug and the vast involvement of the medical community to add to the "generalizable knowledge" of the product.

133. Healthcare providers and Pfizer, Moderna, and Janssen must identify the person receiving the product, monitor their involvement with the product, and report whether or not they had an adverse reaction to the product for the express purpose of adding to the generalizable knowledge of the product.

134. These conditions meet 45 CFR 46, FWA, and the Belmont Report definitions of research activities.

135. The detailed, organized, and methodical way HHS and the CDC structured the nationwide COVID-19 Vaccination Program, it meets the criteria for "a systematic investigation…***designed to develop or contribute to generalizable knowledge***."

[64] 86 Fed. Reg. 5200, 5206-5209.

136. The activities required activities under each COVID-19 EUA and the COVID-19 Vaccination Program Provider Agreement meet the conditions requiring compliance with 45 CFR § 46.101, *et seq*.

137. The CDC COVID-19 Vaccination Program required the State to obtain individuals' private information and adverse events they experienced with the EUA drugs.

138. Oregon owed Fourteenth Amendment obligations to persons considering participation in the federally funded program.

139. Oregon could not delegate its functions to Providence without requiring them also to conduct the research activities.

140. Oregon accomplished this by requiring Providence to sign the CDC COVID-19 Vaccination Program Provider Agreement.

141. Oregon could not delegate that function of distributing the federal government's property without also delegating its legal and Constitutional duties to Providence.

C. Providence is a State Actor.

142. Although Providence, at other times and other circumstances, is a private party, it acted under color of law when, as collaborators with the State of Oregon penalized Crites-Bachert for refusing to inject the federal government's COVID-19 unlicensed EUA/PREP Act drugs into her body.

143. Providence issued a new company policy requiring Crites-Bachert to take COVID-19 vaccines.

144. From the date Providence issued its requirement to become "vaccinated" against COVID-19 to the time it dropped its requirement, no COVID-19 drug licensed and classified by the FDA as a vaccine existed in commerce for Crites-Bachert to comply with Providence's mandate. Providence issued a vaccine mandate but relied exclusively only on FDA-classified investigational new drugs wholly owned by the federal government and only distributed through a federally funded program, which could only be offered under voluntary conditions.

145. Providence was not authorized by any authority to establish conditions regarding the administration of drugs wholly owned by the federal government and under EUA authority.

146. Providence was preempted by the EUA statute and the PREP Act from creating policy that conflicts with the voluntary nature of the CDC COVID-19 vaccination program.

147. After being presented with Providence's ultimatum to inject one of the federal COVID-19 investigational drugs into her body, Crites-Bachert exercised her federally secured right to refuse, at which time Providence unlawfully penalized her, thereby causing her to sustain economic and emotional damages.

148. Crites-Bachert sustained financial, emotional, and legal damages directly related to Providence's depriving her of her Constitutional and federal statutory rights to be free from "sanctions," "coercion," "undue influence," and "unjustifiable pressures" when involved in a federally funded investigational drug, biologic, or device.

149. The State of Oregon voluntarily entered into an agreement with the CDC to administer the federal government's COVID-19 investigational new drugs through its existing immunization program.

150. On August 25, 2021, OHA issued PH 38-2021 Temporary Administrative Rule, which states, "On or before October 18, 2021, healthcare providers and healthcare staff must provide their employer, contractor, or responsible party with either: Proof of vaccination showing they are fully vaccinated; or Documentation of a medical or religious exception."

151. Oregon mandated that all medical workers receive a COVID-19 vaccination.[65] The Centers for Medicare & Medicaid Services (CMS) issued a rule requiring employees of healthcare facilities to be fully vaccinated with a COVID-19 vaccine. These government entities issued a standard of decision mandating certain action by Providence towards its employees.

152. The government vaccination requirements also exerted coercive force. Under Oregon's rule, Providence was subject to a civil penalty of $500 per day per violation. Under CMS rules, Providence would lose substantial reimbursement dollars if it failed to comply. Providence was coerced by the both the federal and state government to impose a vaccine mandate making it a state actor. As a state actor, Providence was also obligated not to violate Crites-Bachert's constitutional and other legal rights, an obligation that it ignored.

[65] OAR 333-019-1010.

153. Providence was involved in joint action with the State to such a degree that they were also in a symbiotic relationship.

154. The State authorized Providence to help it distribute the federal COVID-19 property under the terms and conditions established by the executive branch of the federal government. Providence was bound to comply with the CDC COVID-19 Vaccination Program Provider Agreement.

155. The CDC informed Providence via its COVID-19 Vaccination Program Provider Agreement that:

- Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).
- Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority.
- Organization must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.
- Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.
- Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees.
- Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.

- Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines.

- Organization must comply with CDC requirements for COVID-19 Vaccine management.

- Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS)

- Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.

- Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine.

- Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.

156. Although the COVID-19 Vaccination Program Provider Agreement is a contract between Providence and the CDC, the contract was a required condition by Oregon as a condition for Providence to participate in the CDC COVID-19 Vaccination Program.

157. Moreover, the COVID-19 Vaccination Program Provider Agreement stipulates that Providence "must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine." This includes the required research activities previously discussed as established under the Scope of Authorization for each COVID-19 EUA drug.

158. Providence was completely under the complete control, authority, and directive of the State, which volunteered to administer the federal government's property.

159. Moreover, the federal government warned Providence that "Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine ***outside the parameters of the Program*** constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws." (emphasis added).

160. When Providence issued its Policy requiring the mandatory injection of the federal government's property, they used the "COVID-19 vaccine outside the parameters of the Program."

161. Because the drugs were not only under EUA authorization but also under a federally funded program. The CDC was bound to comply with 45 CFR § 46.122 and 10 U.S.C. § 980, requiring individuals to give their legally effective informed consent in advance of the product's administration.

162. The State was under a legal obligation to obtain Crites-Bachert's legally effective informed consent in accordance with the equal protection of laws and due process as guaranteed to them under the Fourteenth Amendment.

163. The State delegated that function to Providence via its requirement that Providence to sign the CDC Contract pledging to "comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine."

164. The State could not delegate the public function of administering the federal government's COVID-19 EUA property without also delegating its legal and

Constitutional obligations. Therefore, Providence, acting on behalf of the State, owed statutory duties under 21 U.S.C. §360bbb-3, 10 U.S.C. § 980, PREP Act, 45 CFR Part 46, the Belmont Report, and the CDC COVID-19 Vaccination Program Provider Agreement and Fourteenth Amendment Constitutional duties to Crites-Bachert when establishing mandatory conditions of their involvement in the federally funded investigational drugs.

165. **The public function test** is met by (1) Providence exercising powers exclusively held by the federal government and Oregon[66], (2) the power is part of Oregon State's prerogative[67] (the State did not have to volunteer to participate, and Providence operates exclusively under the State's authority), and (3) the power is such that the State itself is obligated to perform due to Governor Brown voluntarily agreeing the State of Oregon to perform for the CDC.[68] "We have, of course, found state action present in the exercise by a private entity of powers traditionally exclusively reserved to the State."[69]

166. **The state compulsion test** is met by the State issuing a mandate impacting Crites-Bachert's employment. Providence is a state actor under this test pursuant to *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982) (citing *Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 166 (1978); *Jackson*, 419 U.S. at 357; *Adickes v. S.H. Kress & Co*., 398 U.S. 144, 170 (1970); *Moose Lodge No. 107 v. Irvis*, 407 U.S. 163, 173 (1965)).

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[66] *Jackson v. Metropolitan Edison Co*., 419 U.S. 345 (1974).
[67] *Flagg Bros., Inc. v. Brooks*, 436 U.S. at 160. *See also Jackson v. Metropolitan Edison Co*., 419 U.S. at 353
[68] *Jackson v. Metropolitan Edison Co*., 419 U.S. 345 (1974).
[69] *Jackson v. Metropolitan Edison Co*., 419 U.S. 345 (1974).

167. **The symbiotic relationship test**[70] is met because:

(1) Oregon was required to obtain Crites-Bachert's legally effective informed consent, and they relied upon the Providence for that function;

(2) Oregon owed Fourteenth Amendment obligations to Crites-Bachert who were delegated to Providence[71];

(3) Oregon and Providence were required to conduct ongoing research activities on behalf of the federal government;

(4) Oregon did not give deference to Providence on how they could conduct the activities of the COVID-19 Vaccination Program and required much of them as previously discussed[72];

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[70] *Brunette v. Humane Society of Ventura County*, 294 F.3d 1205 (9th Cir. 2002): "*Burton* (*Burton v. Wilmington Pkg. Auth*, 365 U.S. 715, 81 S. Ct. 856 (1961)) teaches that substantial coordination and integration between the private entity and the government are the essence of a symbiotic relationship. Often significant financial integration indicates a symbiotic relationship. *See Rendell-Baker v Kohn*, 457 U.S. at 842-43, 102 S.Ct. 2764; *Vincent v. Trend W. Tech. Corp*., 828 F.2d 563, 569 (9th Cir. 1987). For example, if a private entity, like the restaurant in *Burton*, confers significant financial benefits indispensable to the government's "financial success," then a symbiotic relationship may exist. *Vincent*, 828 F.2d at 569. A symbiotic relationship may also arise by virtue of the government's exercise of plenary control over the private party's actions. *See Dobyns v. E-Systems, Inc*., 667 F.2d 1219, 1226-27 (5th Cir. 1982) (finding symbiotic relationship where the government-controlled a private peacekeeping force engaged in a government-directed field mission in the Sinai Peninsula).

[71] In *Giron v. Corrections Corp. of America*, 14 F. Supp. 2d 1245 (D.N.M. 1998), the court stated, "If a state government must satisfy certain constitutional obligations when carrying out its functions, it cannot avoid those obligations and deprive individuals of their constitutionally protected rights by delegating governmental functions to the private sector. *See Terry v. Adams*, 345 U.S. 461, 73 S. Ct. 809, 97 L. Ed. 1152 (1953). The delegation of the function must carry with it a delegation of constitutional responsibilities."

[72] As the court held in *Modaber v. Culpeper Memorial Hospital, Inc*., 674 F.2d 1023 (4tCir. 1982): "we must inquire 'whether there is a sufficiently close nexus between the State and the challenged action of the regulated entity that the action of the latter may fairly be treated as that of the State itself." *Jackson v. Metropolitan Edison Co*., 419 U.S. 345, 351, 95 S.Ct. 449, 453, 42 L.Ed.2d 477 (1974); *accord, Flagg Brothers, Inc. v. Brooks*, 436 U.S. 149, 157, 98 S.Ct. 1729, 1733, 56 L.Ed.2d 185 (1978). In holding that a privately-owned utility's termination of service is not "state action", the Court in *Jackson* makes it clear that state involvement without state responsibility cannot establish this nexus. See 419 U.S. 358, 95 S.Ct. 457. A state becomes responsible for a private party's act if the private party acts (1) in an exclusively state capacity, (2) for the state's direct benefit, or (3) at the state's specific behest. It acts in an exclusively state capacity when it "exercises powers traditionally exclusively reserved to the state[,]" 419 U.S. 352, 95 S.Ct. 454; for

(5) Oregon relied upon private parties to achieve its goal of administering the federal government's COVID-19 property.

168. Private persons, jointly engaged with state officials in the challenged action, are acting "under color" of law for purposes of § 1983 actions."[73] The State's COVID-19 emergency medical countermeasure program is so intimately regulated, licensed, and funded that "The State has so far insinuated itself into a position of interdependence…that it must be recognized as a joint participant in the challenged activity"[74]

169. **The customs test.** The Supreme Court noted in *Adickes v. S. H. Kress & Co*., 398 U.S. 144 (1970) that the "Petitioner will have established a claim under §1983 for violation of her equal protection rights if she proves that she was refused service by respondent because of a state-enforced custom…" (emphasis added).

170. Providence: (1) assured the federal government they would never place an individual under outside pressures to participate in a federally funded research activity via their FWA agreement but did so via their Policy, (2) signed the CDC COVID-19 Vaccination Program Provider Agreement promising to ensure individuals were given the option to accept or refuse, but removed that option via their Policy, (3) was required to obtain Crites-Bachert's legally effective informed consent, but willfully ignored that duty, (4) is assigned an Institutional Review Board requiring them never to place Crites-

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the state's direct benefit when it shares the rewards and responsibilities of a private venture with the state, see id., 357-58, 95 S.Ct. 456-57, *Burton v. Wilmington Parking Authority*, 365 U.S. 715, 723-24, 81 S.Ct. 856, 860-61, 6 L.Ed.2d 45 (1961); and at the state's specific behest when it does a particular act which the state has directed or encouraged."

[73] *Dennis v. Sparks*, 449 U.S. 24 (1980).

[74] *Burton v. Wilmington Pkg. Auth*, 365 U.S. 715, 81 S. Ct. 856 (1961).

Bachert under involuntary conditions when involved in investigational drugs, but required compulsory participation under threat of penalty, (5) has no authority to amend the Scope of Authorization for each COVID-19 EUA drug, but amended the conditions by which the Scope of Authorization is lawful, (6) has no authority to establish conditions contrary to the CDC regarding its administration of the federally owned property, but ignored its duties under 12(a) of the Provider Agreement, (7) has no authority to establish conditions contrary to applicable requirements of any drug under an EUA/EUI, but ignored those applicable requirements, (8) is restricted by the U.S. Congress from using any laws of the State or political subdivision of the State to interfere in the federal government's property by terminating Crites-Bachert's employment exercising a federally secured right to refuse participation in the product's administration, but used the State's at-will laws and the State custom to retaliate against Crites-Bachert's choice of her federally secured option.

171. Providence accomplished its deprivation of rights by acting on a State-enforced custom having the force of law outside of any lawful authority. Providence established and enforced a state custom whereby a person's EUA and PREP Act statutory rights could be ignored "as if" they did not exist. Providence severed its relationship with Crites-Bachert for violating a state-enforced custom, not federal or state law.

172. The State owed constitutional obligations to Crites-Bachert and had full authority to train and educate medical facilities and healthcare workers it licensed of those obligations. Moreover, it had the same authority to enforce the laws, regulations,

and contractual agreements it was under when involving citizens with the federal COVID-19 drug property.

173. The State not only refused to protect Crites-Bachert's rights, but it also established and enforced a custom that was illegal and in direct violation of federal law and the Fourteenth Amendment.

174. Governor Brown and Oregon Health Authority Patrick Allen conspired to establish a State Custom having the force of law replacing federal law and contractual agreements, and in defiance of the Fourteenth Amendment's equal protection and due process guarantees.

175. Providence acted on this State-encouraged and enforced custom when engaging in their unlawful conduct, which led to the deprivation of Crites-Bachert's statutory and Constitutional rights.

176. Providence could only establish a COVID-19 Vaccination Policy because the State agreed to administer the federal COVID-19 property in which it authorized Providence to participate. Therefore, the State and Providence both conspired under a state custom to deprive Crites-Bachert of her Constitutional and statutory rights and privileges because the State and Providence were clothed with the authority of State Power.[75]

[75] Misuse of power, possessed by virtue of state law and made possible only because the wrongdoer is clothed with the authority of state law, is action taken "under color of" state law. *United States v. Classic*, 313 U.S. 299 (1941), *citing Ex Parte Virginia*, 100 U. S. 339, 100 U. S. 346; *Home Telephone & Telegraph Co. v. Los Angeles*, 227 U. S. 278, 227 U. S. 287, *et seq*.; *Hague v. CIO*, 307 U. S. 496, 307 U. S. 507, 307 U. S. 519; cf. 101 F.2d 774, 790.

177. "If a private actor is functioning as the government, that private actor becomes the state for purposes of state action."[76] Providence established mandatory conditions to participate in the State's COVID-19 Vaccination Program that was clothed with the power of a state-enforced custom.

C. The COVID-19 vaccines are experimental drugs.

178. The FDA has authorized emergency use of three investigational vaccines under the Emergency Use Authorization ("EUA") statute.[77] The FDA issued an EUA for the Pfizer investigational vaccine, named Pfizer-BioNTech, on December 11, 2020.[78] The FDA issued an EUA for the Moderna investigational vaccine ("Moderna") on December 18, 2020.[79] The FDA issued an EUA for the Janssen investigational vaccine, on February 27, 2021.[80]

179. Prior to these three investigational vaccines, the FDA has authorized emergency use of only one prior investigational vaccine—for inhaled anthrax. In the case of the anthrax investigational vaccine, a district court issued an injunction forbidding its forced administration to military service members without their informed consent.[81]

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[76] *Terry v. Adams*, 345 U.S. 461, 469-70, 73 S. Ct. 809, 97 L. Ed. 1152 (1953); *See Jackson v. Metropolitan Edison Co.*, 419 U.S. at 353, 95 S. Ct. 449.
[77] 21 U.S.C. § 360bbb-3.
[78] FDA, EMERGENCY USE AUTHORIZATION (EUA) FOR AN UNAPPROVED PRODUCT REVIEW MEMORANDUM, (Dec. 11, 2020) (Pfizer-BioNTech COVID-19 Vaccine), https://www.fda.gov/media/144416/download (viewed July 27, 2023).
[79] FDA, EMERGENCY USE AUTHORIZATION (EUA) FOR AN UNAPPROVED PRODUCT REVIEW MEMORANDUM, (Dec. 18, 2020) (Moderna COVID-19 Vaccine), https://www.fda.gov/media/144673/download (viewed July 27, 2023).
[80] FDA, EMERGENCY USE AUTHORIZATION (EUA) FOR AN UNAPPROVED PRODUCT REVIEW MEMORANDUM, (Feb. 27, 2021) (Janssen COVID-19 Vaccine), https://www.fda.gov/media/146338/download (viewed July 27, 2023).
[81] *Rumsfeld*, 297 F. Supp. 2d at 135.

Importantly, the Court determined that the anthrax investigational vaccine was "experimental," concluding that "the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs.[82]

180. The universal standard for experimental drugs is that they can only be administered after informed consent. The FDA's term "investigational" means the same thing as "experimental." For instance, federal law governing EUA authorization states that the patient has "the option to accept or refuse administration of the [EUA] product."[83]

181. The informed consent standard is repeated in informational material available for each EUA authorized COVID vaccine. For example, every fact sheet for the investigation vaccines states the right of the patient: "Under the EUA, it is your choice to receive or not receive the [Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccine]."[84]

182. The corollary to informed consent is that coercion is not allowed. This is not controversial. For instance, at a CDC published meeting of the official Advisory Committee on Immunization Practices, Executive Secretary Dr. Amanda Cohn, stated on the record (at 1:40:40): "I just wanted to add that, just wanted to remind everybody, that **under Emergency Use Authorization,** and EUA, **vaccines are not allowed to be**

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[82] *Id*.
[83] 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).
[84] Exhibit 2, FDA, PFIZER-BIONTECH INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS, p. 5 (Sept. 22, 2021); Exhibit 4, FDA, MODERNA FACT SHEET FOR RECIPIENTS AND CAREGIVERS, p. 4 (Aug. 27, 2021); Exhibit 6, FDA, JANSSEN FACT SHEET FOR RECIPIENTS AND CAREGIVERS, p. 5 (Aug. 27, 2021).

mandatory. So, early in this vaccination phase, individuals will have to be consented and **they won't be able to be mandated**."[85]

D. The Reported Approval of a Pfizer COVID-19 Vaccine.

183. The terms "authorized" and "approved" are terms of art in the FDA with very different meanings. Drugs may be "authorized" for emergency use, but they remain "unapproved."[86] "A vaccine available under emergency use authorization is still considered investigational." "Approval" refers to the FDA's determination that a drug is safe and effective, and that its benefits outweigh its risks.[87]

184. The well-publicized purported approval of a COVID vaccine by the United States Food & Drug Administration ("FDA") on August 23, 2021, did not do what most people assumed that it did. The Pfizer vaccine originally authorized under the EUA in December 2020 is called Pfizer-BioNTech COVID-19 Vaccine ("BioNTech").[88] On August 23, 2021, the FDA did ***not*** approve BioNTech. Rather, the FDA expressly extended the Emergency Use Authorization for BioNTech: "the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine . . . ."[89]

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[85] CDC, MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES, 1:40:40 (Aug. 26, 2020) (online presentation), https://www.cdc.gov/vaccines/videos/low-res/acipaug2020/COVID-19Supply-NextSteps_3_LowRes.mp4 (viewed July 27, 2023).
[86] *See* 21 U.S.C. § 360bbb(a).
[87] 21 U.S.C. § 355; FDA, ABOUT FDA APPROVAL, (Dec. 29, 2017), https://www.fda.gov/news-events/approvals-fda-regulated-products/about-fda-product-approval (viewed July 27, 2023).
[88] FDA, EMERGENCY USE AUTHORIZATION (EUA) FOR AN UNAPPROVED PRODUCT REVIEW MEMORANDUM, (Dec. 11, 2020) (Pfizer-BioNTech COVID-19 Vaccine), https://www.fda.gov/media/144416/download (viewed Oct. 12, 2023).
[89] Exhibit 6, Letter, FDA to Pfizer, Aug. 23, 2021.

185. What the FDA purportedly approved on August 23, 2021, was a Pfizer vaccine called Comirnaty.[90] But at the same time, the FDA admitted (in a footnote buried on page 5 of its letter) that Comirnaty would not be available to the population.[91] It was later admitted that Comirnaty would never be manufactured. Consequently, Comirnaty is not, and has never been, available at all in the United States.[92] The only Pfizer COVID vaccine available in Oregon is BioNTech—an investigational vaccine. The only COVID-19 vaccines that are available in Oregon are experimental vaccines.

186. In its August 23, 2021 letter, the FDA further distinguished the Pfizer-BioNTech investigational vaccine from the approved Pfizer Comirnaty vaccine. Buried in footnote 8, the FDA states that Pfizer-BioNTech is "legally distinct" from Pfizer-Comirnaty. The FDA further emphasized that all printed matter, advertising, and promotional material for Pfizer-BioNTech clearly and conspicuously state that: "This product has **not been approved** or licensed by the FDA, but has been authorized for emergency use by FDA, under an EUA. . . ."[93]

187. The FDA's August 23, 2021, letter is a model of obfuscation designed to sow confusion and create the misimpression that the Pfizer vaccine was now fully approved and licensed by the FDA. It is Orwellian doublespeak. Providence knew this

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[90] *Id*.
[91] *Id*. at n. 9 ("there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA.")
[92] Fox News, *Sen. Ron Johnson: There is not an FDA approved COVID vaccine in the US* (Oct. 1, 2021), https://www.foxnews.com/media/ron-johnson-no-fda-approved-covid-vaccine (viewed Oct. 13, 2023).
[93] *Id*. at pp. 11-12 (emphasis added).

well. As a result, the vast portion of the public has been fooled into believing that if one went to one's local pharmacy for the Pfizer vaccine, one would be receiving a Pfizer vaccine that was approved and licensed by the FDA, when in fact, the only COVID vaccines available across the country were, and still are, experimental.

188. As an expert in health issues and pharmaceuticals, Providence knew well that the only available vaccines in the United States to satisfy its mandate were experimental vaccines. Under United States law concerning drugs, any use of an experimental drug is an experiment.[94] Providence also knows well that experimental medical products cannot be mandated.

E. The Co-Called COVID-19 "Vaccines" do not Confer Immunity

189. Providence's mandate was based on the premise that immunity from COVID-19 can obtained by being injected by one of the COVID-19 vaccines manufactured by Pfizer, Moderna, or Johnson & Johnson. Providence's premise is false and Providence knew that it was false.

190. These products do not prevent infection by COVID-19 and do not prevent the spread of COVID-19. The CDC has acknowledged that these products do not prevent infection or transmission of COVID-19. The CDC has also acknowledged that the vaccinated and the unvaccinated are equally likely to spread COVID-19.[95] It was known

[94] *See* 21 C.F.R. 312.3.

[95] Catherine M. Brown, et al, *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021*, https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w, (Aug. 6, 2021) (viewed Oct. 13, 2023).

by Providence prior to Providence's mandate, that the COVID-19 vaccines did not confer immunity.

191. Rather than saving people and preventing disease, the COVID vaccines dramatically lengthened the period of time that COVID-19 infections circulated in the population due to antibody dependent enhancement. The so-called COVID vaccines damage human immune systems making humans more susceptible to infection with COVID-19 and other pathogens. People who received the COVID-19 vaccines are more likely to contract COVID-19 than the unvaccinated.

F. Pfizer's trials failed to show safety and efficacy.

192. The original Pfizer trial report showed only 2 months of safety & efficacy data. Pfizer reported that its COVID-19 injection had 95% efficacy. That sounds like that protects you 95% of the time. But that is not what Pfizer's misleading statistic means.

193. The statistic used by Pfizer to fool the public is called relative risk reduction. Relative risk reduction is well-known to be a misleading statistic. As the FDA states: "Patients are unduly influenced when the risk information is presented using a relative risk approach."[96] Which is why the FDA does not approve the use of the relative risk reduction, it recommends absolute risk reduction.

194. One's overall reduction in risk is expressed by the statistic called: absolute risk reduction. The absolute risk reduction calculated in the Pfizer 2-month study for its

[96] Baruch Fischhoff PhD, et al, *Communicating Risks and Benefits*, Food and Drug Administratrion, p. 60 (Aug. 2011) (https://www.fda.gov/files/about%20fda/published/Communicating-Risk-and-Benefits---An-Evidence-Based-User%27s-Guide-%28Printer-Friendly%29.pdf) (visited Oct. 13, 2023).

COVID-19 injection was only 0.84%. Not many people would have taken Pfizer's COVID-19 injection if they had known that their risk reduction was only 0.84%.

195. Providence, as an expert in health and pharmaceutical issues, knows the difference between relative risk reduction and absolute risk reduction. It knew that that advertised effectiveness of the COVID-19 vaccines was fraudulent.

196. Pfizer's 6-month report showed that their experimental COVID-19 injection did more harm than good. Pfizer's 6-month report showed that taking the experimental COVID-19 injection caused more sickness and death than not taking the COVID-19 injection.[97] The 6-month report showed increased risk of illness and ***increased*** death among those who took the experimental COVID-19 injection than those in the placebo group—there were 20 total deaths among those that took the experimental COVID-19 injection and 14 deaths among those in the placebo group.

197. The data from Pfizer's own trial showed that people taking the experimental COVID-19 injection had a 300% increased chance of an adverse event and a 75% increase chance of a severe adverse event.

198. Providence, as an expert in health and pharmaceutical issues, knew or should have known that the vaccines were very dangerous with an unacceptable likelihood of harm.

[97] S.J. Thomas, et al, *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months*, N Engl J Med 2021;385:1761-73 (Sept 15, 2021) (https://www.nejm.org/doi/pdf/10.1056/NEJMoa2110345) (visited Oct. 13, 2023).

199. Healthy young people generally do not die in their sleep. With the COVID-19 injections, people are dying in their sleep on a regular basis. All of these people have one thing in common: recent a recent COVID-19 injection.

200. Indiana life insurance CEO Scott Davidson says that deaths have increased 40% among people ages 18-64.[98] "We are seeing, right now, ***the highest death rates*** we have seen ***in the history of this business*** – not just at OneAmerica," the company's CEO Scott Davison said during an online news conference this week. "***The data is consistent across every player in that business***."[99] Life insurance is a business that studies death rates extensively and relies on its statistical analysis to price policies so that it can turn a profit. A 40% increase in deaths is unheard of. "Just to give you an idea of how bad that is, a three-sigma or a one-in-200-year catastrophe would be 10% increase over pre-pandemic."[100]

201. Providence knew or should have known that the COVID-19 vaccines were extraordinarily dangerous when it mandated them. The irrefutable evidence shows that the COVID-19 vaccines are extraordinarily dangerous. There has never been a medical product offered to the public that compares in danger to the COVID-19 vaccines. Rather than change its policy based on the danger that it knew existed, Providence participated

[98] Melanie Menge, *Indiana life insurance CEO says deaths are up 40% among people ages 18-64*, https://www.thecentersquare.com/indiana/indiana-life-insurance-ceo-says-deaths-are-up-40-among-people-ages-18-64/article_71473b12-6b1e-11ec-8641-5b2c06725e2c.html (Jan. 1, 2022) (viewed Oct. 13, 2023).
[99] *Id*. (emphasis added).
[100] *Id*.

in the massive disinformation campaign to fool the public and its employees into taking a COVID-19 vaccine.

202. What the United States and the World are now experiencing is the unfolding of an unspeakable tragedy caused by the COVID-19 vaccines. There is no doubt that an epidemic of sudden deaths occurred in 2021 and 2022 after the COVID-19 vaccines were released.[101]

203. For every unvaccinated person who dies suddenly approximately 1,000 COVID-19 vaccinated people die suddenly. The rollout of COVID-19 vaccines is the greatest crime against humanity in history.[102] We are witness to a worldwide democide, on a massive scale. A massive portion of the world population has been injected with what amounts to a bioweapon.

204. The COVID-19 vaccines are the cause of a genocide—and Providence is complicit. A spike of 3.2 million additional Americans became disabled in 2021 and 2022. Excess mortality is up 40% all around the world following release of COVID-19 vaccines. An estimated 800,000 Americans have been killed due to the COVID-19 vaccines.[103] The increased death rate in the United States among COVID-19 vaccinated individuals corresponds to about 600,000 excess deaths *per year*; unfortunately, there is

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[101] Edward Dowd, *"Cause Unknown," The Epidemic of Sudden Deaths in 2021 and 2022* (Skyhorse Publishing 2022).

[102] LifeSite News, *'The greatest crime against humanity' in history: Naomi Wolf's 11 revelations from Pfizer vaccine documents*, https://www.lifesitenews.com/news/the-greatest-crime-against-humanity-in-history-naomi-wolfs-11-revelations-from-pfizer-vaccine-documents/ (Apr. 24, 2023).

[103] Vigilant Fox, *Edward Dowd Presents Irrefutable Evidence Vaccine Mandates Killed & Disabled Countless Americans*, https://vigilantfox.substack.com/p/edward-dowd-presents-irrefutable (Mar. 20, 2023) (viewed Oct. 13, 2023).

no sign that the rate of death is decreasing.[104] An estimated 13 million people worldwide have been killed by the COVID-19 vaccines.[105] Another study estimates that the COVID-19 vaccines killed 17 million people worldwide.[106] Providence is one of the entities who participated in and is responsible for this genocide.

205. The COVID-19 vaccines were a predictable and unmitigated catastrophe. The supposed cure was much worse than the disease. Only about 60,000 people died from COVID-19 itself.[107] Providence's COVID-19 vaccine mandate was completely irrational.

G. Human Beings May Not Be Coerced to Take Experimental Medication.

206. Coercing human beings into treatment with experimental medication is forbidden. Human beings have a fundamental right protected under the United States Constitution to not be coerced into medical experimentation.

207. This right grows out of the common law. "At common law, even touching of one person by another without consent and without legal justification was a battery."[108]

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[104] Senator Ron Johnson, COVID-19 Vaccines Roundtable, Testimony of Josh Sterling, https://rumble.com/v1ze4d0-covid-19-vaccines-what-they-are-how-they-work-and-possible-causes-of-injuri.html at 25:15 (Dec. 7, 2022) (viewed Oct. 13, 2023).
[105] Steve Kirsch, *New paper: An estimated 13 million people worldwide killed by the COVID vaccines*, https://stevekirsch.substack.com/p/new-paper-an-estimated-13-million (Feb. 11, 2023) (viewed Oct. 13, 2023).
[106] Denis G. Rancourt et al, *COVID-19 vaccine-asociated mortality in the Southern Hemisphere*, Correlation Research in the Public Interest, Sept. 17, 2023, https://correlation-canada.org/covid-19-vaccine-associated-mortality-in-the-Southern-Hemisphere/ (viewed Jan. 9, 2024).
[107] Reid G. Sheftall, M.D., *How Many People Died in the US during 2020, 2021 and 2022 because of (="From") Covid?*, Nov. 5, 2023, https://drreidsheftall.substack.com/p/how-many-people-died-in-the-us-during (viewed Jan. 9, 2024).
[108] *Cruzan v. Director, Missouri Dept of Health*, 497 U.S. 261, 269 (1990).

In the 19th Century, the Supreme Court has observed "no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."[109]

208. "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment."[110] "Justice Cardozo, while on the Court of Appeals of New York, aptly described this doctrine: 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . .'"[111]

209. All FDA research into experimental drugs requires informed consent from the human subject.[112] The FDA has very specific rules on the necessary elements of informed consent.[113] These elements include the requirement that "participation is voluntary" and that "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled."[114] The Department of Health and Human Services ("HHS"), of which the FDA is a part, has also issued rules mandating the necessary elements of informed consent.[115]

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[109] *Id*. (quoting *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891)).
[110] *Id*.
[111] *Id*. (quoting *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129-130, 105 N.E. 92, 93 (1914).
[112] 21 C.F.R. § 50.20.
[113] 21 C.F.R. § 50.25.
[114] 21 C.F.R. § 50.25(a)(8).
[115] 45 C.F.R. § 46.116.

210. The FDA's draft guidance regarding informed consent for investigational products cites the Belmont report.[116] In 1979, the predecessor agency to the HHS issued the Belmont Report,[117] which was written as a result shocking revelations from the Tuskegee Syphilis Study in which African Americans with syphilis were lied to and denied treatment for more than 40 years.[118]

211. The Belmont Report summarized some of the history of the exploitation of human subjects for experimentation: "during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population."[119]

212. The evolution of explicit prohibitions on coerced medical experimentation on human beings began with the Nuremberg war crimes trials.[120] The prohibition on

[116] FDA, *Informed Consent Draft Guidance* (July 2014), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#coercion (viewed Oct 13, 2023).
[117] HHS, *The Belmont Report* (April 18, 1979), https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf) (viewed Oct 13, 2023).
[118] Kirsh, Danielle, "How the Belmont Report clarified informed consent" (Feb. 8, 2019), https://www.massdevice.com/how-the-belmont-report-clarified-informed-consent/ (viewed Oct. 13, 2023).
[119] The Belmont Report at p. 6.
[120] *Abdullahi v. Pfizer, Inc*., 562 F.3d 163, 177 (2nd Cir., 2009).

nonconsensual medical experimentation on human beings is accepted by nations around the world without significant exception.[121]

213. "The importance that the United States government attributes to this norm is demonstrated by its willingness to use domestic law to coerce compliance with the norm throughout the world."[122]

214. The norm prohibiting nonconsensual medical experimentation on human beings requires, among other things: "**The voluntary consent of the human subject is absolutely essential**. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to **exercise free power of choice, without** the intervention of **any element of force**, fraud, **deceit**, **duress**, over-reaching, or other ulterior form of constraint or **coercion**; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision."[123]

215. In short, human beings have a fundamental right not to be coerced into taking experimental medication.

216. The Nuremberg Code was promulgated as part of the final judgments against doctors who conducted medical experiments without the subjects' consent. "Among the nonconsensual experiments that the tribunal cited as a basis for their

[121] *Id*. at
[122] *Id*. at 182.
[123] The Nuremberg Code, https://history.nih.gov/display/history/Nuremberg%2BCode (viewed Oct. 13, 2023).

convictions were the testing of drugs for immunization against malaria, epidemic jaundice, typhus, smallpox and cholera."[124]

217. The Nuremberg Code was one of the primary sources that the United States Government used to write its laws relating to medical experimentation. "Tellingly, the sources on which our government relied in outlawing non-consensual human medical experimentation were the Nuremberg Code and the Declaration of Helsinki, which suggests the government conceived of these sources' articulation of the norm as a binding legal obligation. Today, FDA regulations require informed consent to U.S. investigators' research, whether conducted domestically or in a foreign country, used to support applications for the approval of new drugs."[125]

218. "The Department of Health and Human Services has compiled the laws, regulations, and guidelines governing human subjects research in eighty-four countries. It is uncontested that all of the countries identified in this compilation require informed consent to medical experimentation."[126]

219. Federal law requires informed consent for the use of EUA products.[127] The EUA statute requires that "individuals to whom the product is administered are informed of the option to accept or refuse administration of the product, of the consequences, if

[124] *Abdullahi*, 562 F.3d at 178.
[125] *Id*. at 181.
[126] *Id.* at 181 n.12 (internal citations omitted).
[127] 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."[128]

220. Providence is well-aware of the requirements for informed consent for experimental medical products and it is contractually obligated to abide by federal informed consent rules. Providence is a signatory of the Federal Wide Assurance agreement in which it agrees to comply with informed consent and other ethical requirements for experimental medical products provided under federal law and the Belmont Report. Providence bound itself to abide by informed consent required by the Belmont Report and other ethical rules when it signed FWA00001033. The main purpose of this FWA agreement is to benefit the third-party human by protecting their rights to informed consent. The intended third-party benefit of the FWA signed by Providence is the preservation of the fundamental human right to accept or refuse experimental medical products without any fear of negative consequences for refusal of an experimental medical product. The purpose of the FWA signed by Providence is to ensure that humans are under no pressure whatsoever to accept an experimental drug.

221. Providence is prohibited, and knows that it is prohibited, from administering experimental drugs to human beings without informed consent. Providence has no authorization to take a different approach with employees. Providence has no authority, and is in violation of law, to compel Crites-Bachert to take an experimental drug without informed consent.

[128] *Id*.

222. Providence is a provider in the CDC vaccination program and signed the CDC COVID-19 Vaccination Program Provider Agreement ("Provider Agreement"). The Provider Agreement provides that, "Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement (Section A)"[129] The Provider Agreement requires the organization to assign a person or persons who will be under a legal obligation to ensure the program is carried out effectively, declaring, "For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements." The Provider Agreement further requires Providence to: "provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative," and "comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine," and "administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws."

223. In the Vaccine Information Fact Sheet for the Pfizer BioNTech investigational vaccine, recipients are told: "Under the EUA, **it is your choice** to receive

[129] Ex. 1.

or not receive the vaccine."[130] In the Fact Sheet for Healthcare Providers Administering Vaccine for the Pfizer BioNTech investigational vaccine vaccination providers are told:

a. "FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is **not an FDA-approved vaccine**;"

b. "The **recipient** or their caregiver **has the option to** accept or **refuse** Pfizer-BioNTech COVID-19 Vaccine;" and

c. "**The significant known and potential risks** and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits **are unknown**."[131]

224. In the Vaccine Information Fact Sheet for the Moderna investigational vaccine, recipients are told: "**It is your choice** to receive or not receive the Moderna COVID-19 vaccine."[132] In the Fact Sheet for Healthcare Providers Administering Vaccine for the Moderna investigational vaccine, vaccination providers are told:

a. the Moderna investigational vaccine "**is not an FDA-approved vaccine**;"

b. "**The recipient** or their caregiver **has the option to** accept or **refuse** the Moderna COVID-19 Vaccine;" and

c. "**The significant known and potential risks** and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits **are unknown**."[133]

[130] Ex. 2.
[131] Ex. 3.
[132] Ex. 4.
[133] Ex. 5.

225. In the Vaccine Information Fact Sheet for the Janssen investigational vaccine, recipients are told: "**It is your choice** to receive or not receive the Janssen COVID-19 Vaccine."[134] In the Fact Sheet for Healthcare Providers Administering Vaccine for the Janssen investigational vaccine, the vaccination provider is told:

a. that the Janssen investigational vaccine "**is not an FDA approved vaccine**;"

b. "**The recipient** or their caregiver **has the option to** accept or **refuse** the Janssen COVID-19 Vaccine;" and

c. "**The significant known and potential risks** and benefits of the Janssen COVID-19 Vaccine, and the extent to which such risks and benefits **are unknown**."[135]

226. Providence is prohibited, and knows that it is prohibited, from administering the experimental COVID-19 vaccines to human beings without informed consent. Providence has no authorization to take a different approach with employees and medical staff. Providence has no authority, and is in violation of law, to compel Crites-Bachert to take an experimental drug without informed consent.

227. Providence is in violation of the immutable law of the United States is that human beings may not be coerced into taking experimental drugs.

[134] Ex. 6.
[135] Ex. 7.

H. The Standard of Review is No Derogation.

228. The United States Supreme Court recognizes a constitutionally protected liberty interest in refusing unwanted medical treatment under the Fourteenth Amendment.[136] "But determining that a person has a 'liberty interest' under the Due Process Clause does not end the inquiry; whether [an individual's] constitutional rights have been violated must be determined by balancing his liberty interests against the relevant state interests."[137]

229. These liberty interests have often been analyzed by the Supreme Court under a heightened scrutiny standard.[138] But a much higher standard applies in the context of experimental drugs. This case involves coercion of human beings to be injected with experimental drugs.

230. The meets and bounds of the liberty interest concerning the coerced use of experimental drugs protected by the United States Constitution is proscribed by the Nuremberg Code. The standard of review that should apply to violations of this liberty interest is no derogation permitted.

231. The fundamental right of human beings not to be coerced into taking experimental medication stands above all other laws. The right does not depend on the consent of a State for its binding force. "The legitimacy of the Nuremberg prosecutions

[136] *Cruzan*, 497 U.S. at 278.
[137] *Id*. at 279.
[138] *See e.g.*, *Riggins v. Nevada*, 504 U.S. 127, 135-136 (1992); *Cruzan*, 497 U.S. at 278-285.

rested not on the consent of the Axis Powers and individual defendants, but on the nature of the acts they committed."[139]

232. The human rights standard established by the Nuremberg Code is a *jus cogens* norm from which no derogation is permitted.[140] 'No derogation permitted' means no deviation from the human rights standard is permitted. *Jus cogens* is mandatory law considered binding on all nations because they are derived from fundamental human values. *Jus cogens* does not depend on the consent of any nation; they recognized as universal rights that are binding on all nations because of the fundamental nature of the human rights that they protect.[141]

233. The standard of review under the Constitution for the right asserted by Crites-Bachert is higher than strict scrutiny because the universal and fundamental right of human beings not to be coerced into taking experimental medication is a right recognized as *jus cogens*.[142] *Jus cogens* is a mandatory norm accepted and recognized by civilized nations from which no derogation is permitted.[143] Providence should not even be permitted to try and rationalize an exception—no derogation of a *jus cogens* norm is permitted. It is inconceivable that there could ever be any sufficient reason for a government to coerce human beings to take experimental medication.

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[139] *Siderman de Blake v. Republic of Argentina*, 965 F.2d 699, 715 (1992).
[140] *See id.* at 714 (1992).
[141] *Id*. at 715.
[142] *See Abdullahi*, 562 F.3d at 179; *Siderman de Blake*, 965 F.2d at 715.
[143] *Id.* at 714; *see also Jus Cogens*, BLACK'S LAW DICTIONARY (10th ed. 2014).

234. Among the charges against doctors at Nuremberg was the nonconsensual testing of drugs for immunization against malaria, epidemic jaundice, typhus, smallpox, and cholera.[144] Could those doctors have had a rationale that would have excused coercing human beings to take experimental medication? The answer is self-evidently: no. Could Providence have a rationale that excuses coercing human beings to take an experimental medication? The answer is still: no. On what legal basis could Providence have a valid excuse for coercing human beings into taking experimental medication in 2021? On what legal basis could Providence have a valid excuse for violating a *jus cogens* human rights norm?

235. The right of Crites-Bachert not to be coerced into taking experimental medication is universal, undeniable, unassailable, and uncompromisable. Coercion of human beings to take experimental medication is forbidden—period.

236. Moreover, Providence may not deny a person the opportunity to work on a basis that infringes her constitutionally protected interests.[145] The "overarching principle, known as the unconstitutional conditions doctrine, . . . vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up."[146]

237. As a direct and proximate result of the Providence's unreasonable and unlawful actions, Crites-Bachert has suffered past damages and will suffer future

[144] *Id*. at 178.
[145] *Perry v. Sinderman*, 408 U.S. 593, 597 (1972).
[146] *Koontz v. St. Johns River Water Mgnt*., 570 U.S. 595, 604 (2013).

damages, both compensatory and general, for which Providence is liable in compensatory, punitive, and all other damages that this Court deems necessary and proper.

238. Because Providence's actions were intentional and willful, Crites-Bachert is entitled to, and hereby demands, an award of punitive damages to deter Providence from repeating its abusive actions.

239. Because Providence's actions involved reckless or callous indifference to Crites-Bachert's rights, Crites-Bachert is entitled to, and hereby demands, an award of punitive damages to deter Providence, from repeating its abusive and unconstitutional actions.

FIRST CLAIM FOR RELIEF

UNLAWFUL RELIGIOUS DISCRIMINATION IN VIOLATION OF THE 1ST AMENDMENT

(42 U.S.C. § 1983)

240. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

241. Crites-Bachert has a bona fide religious belief that conflicted with Providence's vaccine mandate. She informed Providence of her religious belief and the conflict created. Providence first granted a religious exemption, then denied it without explanation. Providence unlawfully discriminated against Crites-Bachert by failing to acknowledge her right to a religious exemption.

SECOND CLAIM FOR RELIEF

ILLEGAL COERCION OF CRITES-BACHERT TO TAKE EXPERIMENTAL MEDICATION IN VIOLATION OF THE DUE PROCESS CLAUSE OF THE 14TH AMENDMENT

(42 U.S.C. § 1983)

242. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

243. The Due Process Clause of the 14th Amendment conveys to the citizenry of the United States the right not to be coerced into taking experimental medication.

244. Crites-Bachert has a constitutionally protected liberty interest to refuse medical treatment under the Due Process Clause of the 14th Amendment. Crites-Bachert's liberty interest means that she is free to exercise her power of choice. No element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion may be used to influence Crites-Bachert to take a COVID injection. Crites-Bachert's right to free exercise of her power of choice for refusing to COVID injections is a human right from which no derogation is permitted.

245. Providence, acting under the color of law, violated Crites-Bachert's right to refuse to take an experimental vaccine. Crites-Bachert suffered economic and non-economic damages.

THIRD CLAIM FOR RELIEF

VIOLATION OF RIGHT TO EQUAL PROTECTION UNDER THE 14TH AMENDMENT

(42 U.S.C. § 1983)

246. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

247. Providence agrees that participants in clinical trials are entitled to informed consent before taking an experimental drug.

248. Providence did not provide Crites-Bachert with informed consent for the experimental COVID-19 vaccine.

249. As a Providence Professional Staff Member, Crites-Bachert was denied the same protection of the law for the experimental COVID-19 vaccines as a participant in a clinical trial.

FOURTH CLAIM FOR RELIEF

VIOLATION OF RIGHT TO INFORMED CONSENT UNDER THE EUA STATUTE

(42 U.S.C. § 1983)

250. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

251. Section 564 of the Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 360bbb-3 ("Section 564") permits the FDA to issue an EUA for a medical product prior to licensure by the FDA.

252. The COVID injections are only authorized under EUAs issued by the FDA.

253. Pursuant to Section 564, entities are prohibited from mandating the use of an EUA product, as Providence has with its vaccine mandate.

254. Section 564's history, statutory framework, and implementation all reflect that "the option to accept or refuse" was intended to continue the longstanding principle that it is not permissible to coerce anyone to receive an unlicensed medical product.

255. Crites-Bachert has the right of informed consent which means she had the absolute right to refuse a COVID injection without any negative consequences.

256. In violation of federal law, Providence failed to acknowledge Crites-Bachert's right to informed consent.

257. Crites-Bachert asserts her rights under federal law against Providence pursuant to 42 U.S.C. § 1983. Providence, acting under the color of law, violated Crites-Bachert's right to refuse to take an experimental vaccine. Crites-Bachert suffered economic and non-economic damages.

FIFTH CLAIM FOR RELIEF

IMPLIED PRIVATE RIGHT OF ACTION 21 U.S.C. § 360bbb-3

258. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

259. Crites-Bachert asserts an implied private right of action under 21 U.S.C. § 360bbb-3. The statute was enacted for the benefit of individuals like Crites-Bachert. The statute does not expressly create or deny a private remedy for denial of informed consent. Recognition of Crites-Bachert's right to a private remedy would not frustrate the

underlying purpose of the legislative scheme. Crites-Bachert's right to informed consent is not an area basically of concern to the States.

260. The Providence's actions have deprived Crites-Bachert of her explicit right to refuse the administration of an emergency use authorized drug without penalty.

SIXTH CLAIM FOR RELIEF

SUBJECTION TO EXPERIMENTAL DRUG USE

(42 U.S.C. § 1983)

261. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

262. The entirety of United States law with regard to experimental medical products, such as the Belmont Report, the ICCPR Treaty, and the Common Rule, stands for the proposition that every human being has the inalienable right to informed consent without any element of coercive force or duress.

263. Providence violated Crites-Bachert's inherent and inalienable right to informed consent, causing her substantial damage.

SEVENTH CLAIM FOR RELIEF

DEPRIVATION OF PROCEDUREAL DUE PROCESS

(42 U.S.C. § 1983)

264. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

265. Providence, having knowledge of Crites-Bachert's Constitutional and federally secured right to refuse administration of EUA drugs and medical products,

intentionally ignored those rights in an attempt to increase the number of participants in the CDC COVID-19 Vaccination Program, resulting in the deprivation of Crites-Bachert's procedural Due Process rights. The fundamental requisite of due process of law is the opportunity to be heard.

266. Crites-Bachert has the Constititional right to present her case and have its merits fairly judged. Providence refused to acknowledge Crites-Bachert's Constitutional and Statutory rights, thereby nullifying impartiality.

267. Providence did not provide Crites-Bachert with a date, time, place, or procedure to defend her right to refuse injection of an unlicensed drug before an impartial body considering their lawful authority to refuse before depriving them of their liberty and property. worseProvidence's actions deprived Crites-Bachert of her right to procedural due process.

EIGHTH CLAIM FOR RELIEF

BREACH OF CONTRACT

268. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

269. Crites-Bachert was party to a contract with Providence. Crites-Bachert was a Providence Staff member subject to requirements in exchange for the privilege to have access to Providence Facilities. The requirements were specified in the Providence Oregon Professional Staff Bylaws and Providence Oregon Professional Staff Policies and

Procedures.[147] Providence benefited from having Crites-Bachert on staff by having a highly competent professional who could provide services to hospital patients. Providence compensated for emergency room coverage. Providence collected fees when surgeries performed by Crites-Bachert were performed in Providence's facilities. The parties had mutual obligations with mutual consideration. Their relationship was contractural.

270. Providence did not have the right to unilaterally modify the contract to require Crites-Bachert to take an experimental drug.

271. Providence breached its contract with Crites-Bachert by terminating her privileges at Providence.

NINTH CLAIM FOR RELIEF

BREACH OF CONTRACT, THIRD PARTY BENEFICIARY

272. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

273. The CDC COVID Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR 46, 21 U.S.C. §360bbb-3, Title 21 of the US Code, the EUA Scope of Authorization letter clearly and unambiguously create third-party beneficiary rights, namely the right to informed consent.

274. Providence's actions violated Crites-Bachert's right to the intended benefits of the United States' laws, namely her right to informed consent for experimental drugs.

[147] https://www.providence.org/locations/or/medical-staff-services

TENTH CLAIM FOR RELIEF

TORTIOUS INTERFERENCE

275. Crites-Bachert realleges and incorporates by reference the foregoing allegations as if fully set forth herein.

276. Providence knew that Crites-Bachert had existing business and prospective business that depended on her admitting privileges. Providence intentionally interfered with Crites-Bachert's current and future business relationships by unilaterally imposing a vaccination requirement and terminating Crites-Bachert's privileges. Providence's termination of Crites-Bachert's privileges have been the direct cause of Crites-Bachert's lost business and lost future business.

277. Crites-Bachert has been damaged by Providence's tortious interference with Crites-Bachert's existing and prospective business.

ELEVENTH CLAIM FOR RELIEF

IRRATIONAL SANCTION

(42 U.S.C. § 1983)

278. "The Due Process and Equal Protection Clauses already protect individuals from sanctions which are downright irrational. The Eighth Amendment protects against excessive civil fines, including forfeitures."[148]

279. Providence applied a sanction that prevented Crites-Bachert from practicing her licensed profession in Oregon. A sanction so severe that it can only be viewed as

[148] *Hudson v. United States*, 522 U.S. 93, 103 (1997)

corporal punishment of one's career, requiring it to come under the purview of the Eighth Amendment.

280. When Providence and the State conspired in the joint action of terminating Crites-Bachert the sanction acted as punishment instead of a State's police power meant to encourage behavior. The consquences to Crites-Bachert were excessive by any standard courts have used when reviewing the actions of a government against a charged felon, much less an individual charged with a civil infraction.

281. Providence applied a terminal punishment in violation of the Excessive Fines Clause.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Crites-Bachert respectfully demands a jury trial of all issues triable to a jury in this action.

PRAYER FOR RELIEF

WHEREFORE, Crites-Bachert prays for judgment against Providence as follows:

A. judgment for economic and non-economic damages against Providence;

B. punitive damages against Providence;

C. attorneys' fees and costs; and

D. such other and further relief that the Court deems just.

Respectfully submitted,

Dated: January 9, 2024

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